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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/870,276      | 05/30/2001  | Carsten Gerner Larsen | NN-6251.200 US      | 7411             |

26137 7590 07/16/2002

PATENT DEPARTMENT  
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP  
FOUR TIMES SQUARE  
NEW YORK, NY 10036

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| EXAMINER |
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NGUYEN, TU C

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| ART UNIT | PAPER NUMBER |
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3749

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,276

Applicant(s)

LARSEN ET AL.

Examiner

Tu C. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12 is/are rejected.
- 7) ☒ Claim(s) 8-11 and 13-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Preliminary Amendment***

This Office Action is in response to the Preliminary Amendment filed on February 28, 2002.

### ***Claim Objections***

Claims 8-11 and 13-17 are objected to under 37 CFR 1.75(c) as being in improper form because these are of improper multiple dependent form. See MPEP § 608.01(n). The multiple dependencies must be in the alternative only and a claim that is multiply dependent cannot depend on a claim that also is multiply dependent. Accordingly, the claims 8-11 and 13-17 have not been further treated on the merits.

Claims 1-17 are objected to because of the following informalities: the term “characterized” should not be underlined. Appropriate correction is required.

It appears that the terms “sharpe” and “irreversible” in claim 1 and the term “subcutis” in claims 2-3 are typographical errors. Applicant might intended for “sharp,” “irreversibly,” and “subcutaneous,” respectively. Applicant is requested to clarify the subject matter.

It appears that the term “are” as recited in claim 12 in line 30 might have been indented for the term “is.” Application is requested to clarify the subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification as filed does not disclose nor suggest a disposable double pointed injection needle wherein the needle cannula is fastened to the needle hub without the centrally hub tower.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitations "relatively thin" in line 4 and "firmly" in line 6, claim 5 recites the limitation "a number" in line 16, claim 12 recites the term "firmly" in line 29. These terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As regard the term "a number" in claim 5, Applicant is further requested to clarify whether this term is referred to a number or expressed as plurals form. If former, applicant is requested to specify it.

Claim 2 recites the limitation "a major part" in lines 29 and 34. There is insufficient antecedent basis for this limitation in the claim. Applicant is requested to clarify the subject matter.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

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§ 2172.01. The omitted elements are: the tower hub referenced by numeral (15) that which appears to be the essential structural element necessary for fastening the needle cannula in the needle hub as claimed.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between needle hub and the needle cannula is not well defined as claimed. Applicant is requested to specify how and where the needle cannula is fastened in the needle hub such as (1) is the needle cannula adjacent to needle hub or (2) is the needle cannula is fastened in the needle hub through an intermediate element such as the hub tower (15) as specified in the specification on page 13 lines 8 to 15.

In view of the indefiniteness of claims as recited, the claims therefrom is further rejected, as best can be understood, as follows:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohammad (U.S. Patent No. 6,162,197). Mohammad discloses a retractable needle assembly comprising elements

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as recited in these claims (Abstract, figures 5-8, column 2 lines 56-60, column 5 lines 59-67, column 6 lines 1-23 and 45-65, column 7 lines 11-32).

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Chanoch (U.S. Patent No. 5,674,204). Chanoch discloses an insulin delivery pen having a cap-actuated clutch comprising elements as recited in this claim (figure 1-2 and 4, column 1 lines 37-39, column 2 lines 34-38, column 4 lines 13-41, column 6 lines 30-55).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tu C. Nguyen whose telephone number is 703-305-0537. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on 703-308-1935. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Tu C. Nguyen  
July 13, 2002

  
DENISE VESQUIEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700